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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,403	10/31/2000	Jesse A. May	1700 F US	8448

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EXAMINER

KIFLE, BRUCK

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,403

Applicant(s)

May et al.

Examiner

Bruck Kifle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 29, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above, claim(s) 3, 4, 7, 8, 11, 12, 15, 16, 19, 20, 23, 24, 27-33, 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 9, 10, 13, 14, 17, 18, 21, 22, 25, 26, 34, 39, 40, 43, 44, a is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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Election/Restriction

Applicant's election of group I (claims 1, 2, 5, 6, 9, 10, 13, 14, 17, 18, 21, 22, 25, 26, 34, 39, 40, 43, 44 and 47, drawn to compounds, pharmaceutical compositions and method of use of the compound of claim 1) in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3, 4, 7, 8, 11, 12, 15, 16, 19, 20, 23, 24, 27-33, 35-38, 41, 42, 45, 46, 48 and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group.

Applicants are reminded that compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.475(d).

Claim Rejections - 35 USC § 112

Claims 1, 2, 5, 6, 9, 10, 13, 14, 17, 18, 21, 22, 25, 26, 34, 39, 40, 43, 44 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) It is unclear which atoms make-up the monocyclic heteroaromatic group denoted by "Aryl." It is not known which atoms are present, how many of each is present, what size ring is intended, etc. A clarification is required.

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ii) Appropriate punctuation is required in the definitions of the variables. For example, R¹ is defined as “H, OH, OC₁₋₃alkyl, C₁₋₃alkyl, C₁₋₃alkyl substituted optionally with OH, or OC₁₋₃alkyl.”

It is unclear whether there are 4, 5 or 6 different possibilities present. It is suggested to rewrite this as, for example, “R¹ is H, OH, OC₁₋₃alkyl or C₁₋₃alkyl optionally substituted by OH or OC₁₋₃alkyl”. Thus, the last term is part of the definition and does not create ambiguity whether OC₁₋₃alkyl is a substituent on the alkyl or is part of R¹. Also, alkyl, optionally substituted, permits for unsubstituted alkyl. Finally, inserting “or” before the last possibility distinguishes one variable from another.

iii) In the definition of R⁷ and R⁸ as “R⁷, R⁸ are together with the nitrogen atom to which they are attached incorporated into a heterocyclic ring of 5 to 8 atoms which may include a second heteroatom selected from N, O, S, such as” it is unclear whether the ring formed is monocyclic, polycyclic, saturated, unsaturated, etc.. Also, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

iv) The last phrase of each claim should read “or a pharmaceutically acceptable salt or solvate thereof” to be of proper Markush language presenting the possibilities in the alternative.

v) It is unclear which retinal diseases are intended in claims 13 and 14. A clarification is required because there are retinal diseases that are not treatable pharmacologically (detached retina) and those that are caused by different diseases (diabetes).

vi) Claim 34 improperly depends from claim 1.

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Claims 17, 18, 21, 22, 25, 26, 43 and 44 are objected to under 37 CFR 1.75 as being a substantial duplicate of each other. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). All of these claims are drawn to the same composition. The intended use is irrelevant because it does not carry any patentability weight.

Copious amount of art was found that anticipates or renders obvious the instant claims. Exemplary rejections are made.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 17, 18, 21, 22, 25, 26, 39, 40, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Loev (US 3,303,189). The claims read on the compound of example 13

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on column 5 (RN 13618-03-6P) and it's method of use as CNS depressant (see col. 1, lines 11-15).

Claims 1, 2, 17, 18, 21, 22, 25, 26, 39, 40, 43 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Mizuno et al. (US 6,271,223). The claims read on the compound of example 29 on column 35 (Table 6).

Claims 1, 2, 5, 6, 9, 10, 13, 14, 17, 18, 21, 22, 25, 26, 34, 39, 40, 43, 44 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al. (US 5,538,966). The claims read on the compounds of example 5 and it's method of use. as CNS depressant (see col. 1, lines 11-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 17, 18, 21, 22, 25, 26, 39, 40, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loev (US 3,303,189). The reference teaches a generic group of compounds which embraces applicants' claimed compounds (see col. 2, lines 14-36, compounds of formula II and definitions of the variables). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the

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skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Claims 1, 2, 5, 6, 9, 10, 13, 14, 17, 18, 21, 22, 25, 26, 34, 39, 40, 43, 44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. (US 5,538,966). The reference teaches structurally similar compounds. The claims differ by requiring the linker "n" to be 2 to 4 over the closest prior art compound of example 4 which has n=1. However, it has been long established that structural relationship varying the size of a linking carbon chain - is per se obvious. Specifically, *In re Shetty*, 195 USPQ 753, *In re Wilder*, 195 USPQ 426 and *Ex Parte Greshem* 121 USPQ 422 all feature a compound with a C₂ link rejected over a compound with a C₁ link. Similarly, *In re Chupp*, 2 USPQ 2nd 1437 and *In re Coes*, 81 USPQ 369 have a C₁ link unpatentable over a C₂ link. *Ex parte Ruddy* 121 USPQ 427 has a C₃ link unpatentable over a C₁ link. *Ex parte Nathan*, 121 USPQ 349 found the insertion of a C₂H₄ link obvious. In all of these cases, the variation was per-se obvious and did not require a specific teaching.

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Information Disclosure Statement

The information disclosure statement filed with the application fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been fully considered. All of the journal articles (references AR, AS, AT, BR, BS, BT, CR, CS, CT, DR, DS, DT, ER, ES, ET, FR, FS, FT, GR, GS, GT, HR, HS, HT and IR) and PCT publications 9800400 and 9220338 are missing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

February 6, 2002


Bruck Kifle
Primary Examiner
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